## REMARKS

Claims 1-8 are pending in the present application. Claims 1-8 are rejected under the judicially created doctrine of obviousness-type double patenting. Applicants respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of the amendments and remarks below.

### The Invention

The present invention provides novel condensation drug aerosols and methods for producing such aerosols. These condensations aerosols have little or no pyrolysis degradation products. The unique method for generating or producing such aerosols employs rapid vaporization of the drug to minimize drug degradation during the process. These vaporized drugs are subsequently condensed to form particles of a desirable particle size for inhalation. These aerosols are especially useful in the treatment of acute or chronic conditions wherein rapid onset of treatment is desirable.

### The Amendments to the Specification

The specification has been amended, at paragraphs **[0007]** and **0017]**, to correct a typographical error by replacing 200 μ with 200 μg.

The specification has been amended, at paragraph **[0074]**, to note a calculated thickness of a diazepam thin layer, on a 78.5 $cm^2$ aluminum-foil solid support, of about 1.3 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0075]**, to note a calculated thickness of a diazepam thin layer, on a 24 $cm^2$ aluminum-foil solid support, of about 2.2 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0076]**, to note a calculated thickness of a diazepam thin layer on a 36 $cm^2$ aluminum-foil solid support of about 5.1 microns, based on an assumed drug density of 1g/cc.

The specification has been amended, at paragraph **[0078]**, to note a calculated thickness of a diazepam thin layer on a 36 $cm^2$ aluminum-foil solid support of about 1.4 microns, based on an assumed drug density of 1g/cc

The amendments to the specification at paragraphs **[0007]** and **[0017]** correct typographical errors that are clear from context. The amendments to the specification at paragraphs **[0074]** to **[0078]** parallel the amendments that were made with respect to the parent U.S. patent application Serial No. 10/150,056, now U.S. Patent No. 6,805,853.

It is well-established in the case law that amendatory material is not new matter where it is

concerned with an inherent characteristic of an illustrative product of an invention already sufficiently identified in the original patent disclosure. (*In re Nathan, Hogg, and Schneider*, 140 USPQ 601 (CCPA, 1964); In *In re Reynolds*, 170 USPQ 94 (CCPA 1971) the CCPA cited with approval the following holding from *Technicon Instruments Corp. v. Coleman Instruments, Inc.*, 255 F. Supp. 630, 150 USPQ 227 (N.D. Ill. 1966):

> By disclosing in a patent application a device that inherently performs a function, operates according to a theory, or has an advantage, a patent applicant necessarily discloses that function, theory, or advantage even though he says nothing concerning it. The application may be amended to recite the function, theory, or advantage without introducing prohibited new matter.

This principle has been endorsed by the CAFC, e.g., in *Kennecott Corp., v. Kyocera Int'l l Inc.*, 835 F. 2d. 1419, 5 USPQ2d 1194 (Fed. Cir. 1987).

The amendatory material regarding the assumed density of the drugs is already stated in the specification, e.g., see paragraph **[0076]** which states " . . . multiplied by the density of the drug (taken to be 1 $g/cm^3$)." Additionally, the thickness of the coating would be readily derivable by a person skilled in the art of the claimed invention by multiplying the mass of the material by its density and then dividing this by the surface area over which it is coated. As stated above information regarding the density is readily available from the specification and other recognized sources (e.g., the CRC Handbook of Chemistry and Physics, the Aldrich Chemical Catalog, etc.) and can be assumed to about 1g/cc. The drug masses and substrate areas are also disclosed in the specification. This information is all that is needed for one to calculate the thickness.

Thus, no new matter is introduced by these amendments to the specification. The Examiner is respectfully requested to enter the amendments to the specification.

**The Amendments to the Claims**

Without prejudice to the Applicants' rights to present claims of equal scope in a timely filed continuing application, to expedite prosecution and issuance of the application, the Applicants have amended Claims 1-8. The Applicants also have presented new Claims 9-22. The amended claims and the new claims are supported by the specification (see below for examples of such support).

| Claim | Examples of Support in the Specification |
|---|---|
| Claim 1 | Paragraphs 0005, 0008, 0012, 0014; Examples 1-4 |
| Claim 2 | Paragraph 0024 |
| Claim 3 | Paragraph 0024 |
| Claim 4 | Paragraph 0008 |
| Claim 5 | Paragraphs 0005, 0008, 0012, 0014; Examples 1-4 |
| Claim 6 | Paragraph 0024 |

| Claim | Examples of Support in the Specification |
|---|---|
| Claim 7 | Paragraph 0024 |
| Claim 8 | Paragraph 0008 |
| Claim 9 | Paragraph 0012; Table 1 |
| Claim 10 | Paragraph 0012 |
| Claim 11 | Paragraph 0012; Table 1 |
| Claim 12 | Paragraph 0008 |
| Claim 13 | Examples 1-4 |
| Claim 14 | Paragraph 0055 |
| Claim 15 | Paragraph 0012; Table 1 |
| Claim 16 | Paragraph 0012 |
| Claim 17 | Paragraph 0012; Table 1 |
| Claim 18 | Paragraph 0008 |
| Claim 19 | Examples 1-4 |
| Claim 20 | Paragraph 0055 |
| Claim 21 | Paragraphs 0005, 0008, 0012, 0014; Examples 1-4 |
| Claim 22 | Paragraphs 0005, 0008, 0012, 0014; Examples 1-4 |

The amendments to the claims do not introduce new matter. Applicants respectfully submit that the amendments to the claims put the case in condition for allowance. The Examiner is respectfully requested to enter the amendments to the claims and allow all amended claims.

**Double Patenting**

Claims 1-8 were rejected under the judicially created doctrine of obviousness-type double patent as being unpatentable over claims of U.S. Patent No. 6,805,853 B2, as these claims are "either anticipated by, or would have been obvious over, the reference claims." Office Action at 2-3. Also, Claims 1-4 were provisionally rejected under the doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application Nos. 10/792,001 and 10/718,982. *Id.* at 3-4.

Applicants have filed with this response Terminal Disclaimers with regard to U.S. Patent No. 6,805,853 B2 and copending Application Nos. 10/792,001 and 10/718,982. Applicants believe that this addresses the Examiner's concerns and respectfully request reconsideration of the application, withdrawal of all rejections, and allowance of the application in view of these actions and remarks.

**Conclusion**

The Applicants appreciate the Examiner's careful and thorough review of the application and submit that the Examiner's concerns have been addressed by the amendments and remarks above. The Applicants accordingly request the Examiner to withdraw all rejections and allow the application. In the event the Examiner believes a telephonic discussion would expedite allowance or help to resolve outstanding issues, prosecution of the application, then the Examiner is invited to call the undersigned.

This constitutes a request for any needed extension of time and an authorization to charge all fees therefore to deposit account No. 19-5117, if not otherwise specifically requested. The undersigned hereby authorizes the charge of any fees created by the filing of this document or any deficiency of fees submitted herewith to be charged to deposit account No. 19-5117.

Respectfully submitted,

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